APR - 6 2011

# 510(k) SUMMARY
# K103604

1. 510(k) Owner Name and Address:
   PHASEIN AB
   Svärdvägen 15
   182 33 Danderyd
   Sweden
   Telephone: 46-8-544-98-150
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2. Contact Person:
   David Weissburg
   Weissburg Associates
   4213 Winnequah Dr.
   Madison, Wisconsin, 53716 USA

3. Date prepared: November 30, 2010

4. Trade Name: Infrared Sidestream gas Analyzer (ISA), model/catalogue numbers 800101, 800601 and 800401

5. Common Name: Multigas Monitor

6. Classification Names: Carbon-dioxide gas analyzer (21 CFR 868.1400, Product Code CCK)

7. Substantially equivalent to: Datex-Ohmeda S/5 (K051092)

8. Device Description: ISA is a sidestream respiratory gas analyzer based on infrared gas spectrometry. It is intended to be connected to a Host/Backboard Device for display of respiratory parameters. ISA is connected to the patient breathing circuit via the Nomoline sampling line that includes a water separation section and a bacteria filter.

   The following ISA models are available:

a) ISA CO2 (model/catalogue number 800101), measurement of $CO_2$.

b) ISA AX+ (model/catalogue number 800601), measurement of $CO_2$, $N_2O$ and 5 Anesthetic agents with automatic agent identification

c) ISA OR+ (model/catalogue number 800401), measurement of $CO_2$, $O_2$, $N_2O$ and 5 Anesthetic agents with automatic agent identification (includes paramagnetic oxygen sensor).

   The ISA product family also includes the disposable Nomoline sampling line. A clamp adapter and modura holder are offered as optional accessories.

9. Indications for Use:

   The ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for display of real time and derived monitoring data of the following breathing gases:

   ISA CO2: $CO_2$

   ISA AX+: $CO_2$, $N_2O$, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

   ISA OR+: $CO_2$, $O_2$, $N_2O$, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

   ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

10. Comparison to predicates: The ISA model/catalogue numbers 800101, 800601 and 800401 have the same gas measurement capabilities as its predicate device. The ISA uses the same basic technology concepts used in the predicate device, while adding improvements derived from advanced electronics and miniaturization. The intended use of the ISA and its predicate are the same. All the devices consume equivalent amounts of electric power and utilize disposable single-patient-use connections to interface with gases in the breathing circuit. Labeling and materials used are equivalent.

11. Testing vs. predicates: Testing in direct comparison to predicates throughout the operating range was conducted using calibrated gas samples and legally marketed anesthesia and ventilation devices.

12. Conclusions from testing: The ISA, models 800101, 800601 and 800401 demonstrated performance, safety and effectiveness equivalent or superior to its predicate in all characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Phasein AB
C/O Mr. David Weissburg
Official Correspondent
Weiss burg Associates
4213 Winnequah Drive
Madison, Wisconsin 53716

APR -6 2011

Re: K103604
Trade/Device Name: ISA-Infrared Sidestream Gas Analyzer
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: March 28, 2011
Received: March 29,2011

Dear Mr. Weissburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default .htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number: K103604

Device Name:
ISA – Infrared Sidestream gas Analyzer.

Indications for Use:

The ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO2: $CO_2$

ISA AX+: $CO_2$, $N_2O$, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: $CO_2$, $O_2$, $N_2O$, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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